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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,256	09/13/2005	Angus Moodycliffe	112701-818	3290

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EXAMINER	
SHIN, DANA H	

ART UNIT	PAPER NUMBER
1635	

NOTIFICATION DATE	DELIVERY MODE
08/13/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/525,256	MOODYCLIFFE ET AL.	
	Examiner	Art Unit	
	DANA SHIN	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6 and 7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

This Office action is in response to the communications filed on June 4, 2009.

Currently, claims 1-3 and 6-7 are pending and under examination on the merits in the instant case.

The following rejections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 102

Claims 1 and 3 remain rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Walkley et al. for the reasons of record as set forth in the Office action mailed on February 23, 2009 and for the reasons stated below.

Applicant's arguments filed on June 4, 2009 have been fully considered but they are not persuasive. Applicant argues that amending the claims to recite a "cosmetic product" is sufficient

to overcome this rejection because Walkley et al. do not teach or suggest a "cosmetic product". Contrary to applicant's argument, the mere addition of the term "cosmetic product" is not sufficient to overcome the instant rejection because the preamble language reciting functional limitations "A cosmetic product for preventing or treating epithelial tissue damage" is still interpreted as intended use for examination purpose as with "A composition for preventing or treating epithelial tissue damage" recited previously. Note that the instant claims are "product" claims and the patentability of the product claims depends on the material/element that constitutes the product. In the instant case, the RNA antisense molecule that is targeted to glucosylceramide synthase further comprising a pharmaceutically acceptable carrier of Walkley et al. meets every structural limitation set forth in the product claims. Furthermore, applicant has not provided any evidence showing that the RNA antisense molecule composition of Walkley et al. is incapable of performing the functional role intended and recited by the claims. Instead, applicant asserts that the instantly claimed "cosmetic product" is different from a pharmaceutical composition because "pharmaceutical compositions are generally referred to as medicine or a medicament" especially for "internal" organs in the body, whereas cosmetic products are for "outside" for improving appearances. This unfounded, extremely generalized characterization of pharmaceutical compositions and cosmetic products is irrelevant to the claims at issue in the instant case. As explicitly stated by applicant, the claimed cosmetic product embraces "sun-blockers". See page 5 of the remarks. As such, the cosmetic product claimed in the instant case inevitably reads on and is embraced by pharmaceutical compositions because as clearly stated by applicant, pharmaceutical compositions are used to mitigate or treat a condition, such that a sun blocker mitigates sun damage that contributes to skin cancer. Furthermore, applicant's own

distinction between a pharmaceutical composition and a cosmetic product by virtue of treating "inside" or "outside" is completely arbitrary since one can apply a pharmaceutical composition on the body (not internal organ) to treat skin conditions. Furthermore, applicant expressly acknowledges that Walkley et al. also taught that the antisense compound can be formulated for intradermal pharmaceutical composition. See page 5-6 of the remarks. Hence, it inherently and logically flows that the intradermal formulation product comprising an anti-glucosylceramide synthase antisense RNA compound of Walkley et al. not only satisfies the structural limitations but also the "intended" functional language recited in the claims.

Again, since applicant has failed to show that the composition of Walkley et al. does not inherently possess the functional characteristics of the claimed product, this rejection is maintained.

Claims 1 and 3 remain rejected under 35 U.S.C. 102(a) as being anticipated by Di Sano et al. for the reasons of record as set forth in the Office action mailed on February 23, 2009 and for the reasons stated below.

Applicant's arguments filed on June 4, 2009 have been fully considered but they are not persuasive. Applicant argues that amending the claims to recite a "cosmetic product" is sufficient to overcome this rejection because Di Sano et al. do not teach or suggest use of a "cosmetic product". Contrary to applicant's argument, the current claim amendment is insufficient to overcome this rejection because the antisense composition of Di Sano et al. meets every structural limitation required by the claims and therefore the composition of Di Sano et al. must inherently perform as a cosmetic product for treating epithelial tissue damage. Furthermore,

applicant has failed to submit any evidence showing that the composition of Di Sano et al. is incapable of performing the intended functions recited in the claims. Hence, this rejection is maintained.

Claims 1 and 3 remain rejected under 35 U.S.C. 102(a) as being anticipated by Deng et al. for the reasons of record as set forth in the Office action mailed on February 23, 2009 and for the reasons stated below.

Applicant's arguments filed on June 4, 2009 have been fully considered but they are not persuasive. Applicant argues that amending the claims to recite a "cosmetic product" is sufficient to overcome this rejection because Deng et al. do not teach or suggest use of a "cosmetic product". Contrary to applicant's argument, the current claim amendment is insufficient to overcome this rejection because the antisense composition of Deng et al. meets every structural limitation required by the claims and therefore the composition of Deng et al. must inherently perform as a cosmetic product for treating epithelial tissue damage. Furthermore, applicant has failed to submit any evidence showing that the composition of Deng et al. is incapable of performing the intended functions recited in the claims. Hence, this rejection is maintained.

Claims 1 and 3 remain rejected under 35 U.S.C. 102(e) as being anticipated by Dwek et al. for the reasons of record as set forth in the Office action mailed on February 23, 2009 and for the reasons stated below.

Applicant's arguments filed on June 4, 2009 have been fully considered but they are not persuasive. Applicant argues that amending the claims to recite a "cosmetic product" is sufficient

to overcome this rejection because Dwek et al. do not teach or suggest use of a "cosmetic product". Contrary to applicant's argument, the current claim amendment is insufficient to overcome this rejection because the antisense composition of Dwek et al. meets every structural limitation required by the claims and therefore the composition of Dwek et al. must inherently perform as a cosmetic product for treating epithelial tissue damage. In addition, as pointed out by applicant, Dwek et al. taught intradermal formulation the anti-glucosylceramide synthase antisense RNA molecule. Hence, it inherently and logically flows that the intradermal formulation product comprising an anti-glucosylceramide synthase antisense RNA compound of Dwek et al. not only satisfies the structural limitations but also the "intended" functional language recited in the claims. Furthermore, applicant has failed to submit any evidence showing that the composition of Dwek et al. is incapable of performing the intended functions recited in the claims. Hence, this rejection is maintained.

Claims 1 and 3 remain rejected under 35 U.S.C. 102(b) as being anticipated by Cabot et al. for the reasons of record as set forth in the Office action mailed on February 23, 2009 and for the reasons stated below.

Applicant's arguments filed on June 4, 2009 have been fully considered but they are not persuasive. Applicant argues that amending the claims to recite a "cosmetic product" is sufficient to overcome this rejection because Cabot et al. do not teach or suggest use of a "cosmetic product". Contrary to applicant's argument, the current claim amendment is insufficient to overcome this rejection because the antisense composition of Cabot et al. meets every structural limitation required by the claims and therefore the composition of Cabot et al. must inherently

perform as a cosmetic product for treating epithelial tissue damage. Furthermore, applicant has failed to submit any evidence showing that the composition of Cabot et al. is incapable of performing the intended functions recited in the claims. Hence, this rejection is maintained.

Claims 1 and 3 remain rejected under 35 U.S.C. 102(b) as being anticipated by Liu et al. for the reasons of record as set forth in the Office action mailed on February 23, 2009 and for the reasons stated below.

Applicant's arguments filed on June 4, 2009 have been fully considered but they are not persuasive. Applicant argues that amending the claims to recite a "cosmetic product" is sufficient to overcome this rejection because Liu et al. do not teach or suggest use of a "cosmetic product". Contrary to applicant's argument, the current claim amendment is insufficient to overcome this rejection because the antisense composition of Liu et al. meets every structural limitation required by the claims and therefore the composition of Liu et al. must inherently perform as a cosmetic product for treating epithelial tissue damage. Furthermore, applicant has failed to submit any evidence showing that the composition of Liu et al. is incapable of performing the intended functions recited in the claims. Hence, this rejection is maintained.

Claim Rejections - 35 USC § 112

Claims 1-3 and 6-7 remain rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement for the reasons of record as set forth in the Office action mailed on February 23, 2009 and for the reasons stated below.

Applicant's arguments filed on June 4, 2009 have been fully considered but they are not persuasive. Applicant argues that the instant specification provides "sufficient information" regarding the claimed subject matter (e.g., glucosylceramide synthase is associated with epithelial tissue damage) and therefore one can make and use the claimed product without undue experimentation. First, it is noted that this rejection is based on the claim interpretation that is different from the prior art rejections such that the preamble intended use language is given full patentable weight in the instant rejection. Second, contrary to applicant's argument, as repeatedly pointed out in previous Office actions, the instant specification does not at all provide sufficient information on the functional roles of glucosylceramide synthase with regard to epithelial tissue damage, nor does it disclose a single working example either *in vitro* or *in vivo* that an antisense against glucosylceramide synthase indeed results in the reduction of epithelial tissue damage. Again, just to recapture the content of the disclosure of the instant specification, applicant's attention is directed to the fact that the instantly claimed target gene glucosylceramide synthase appears only once on page 10 as part of a generic statement: "To this end, the number of the glucosylceramide synthase transcripts may be reduced by designing an polynucleotide antisense to at least a part of the glucosylceramide synthase gene or glucosylceramide synthase mRNA, so that eventually the signal to epithelial cells to proliferate is turned down." There is nothing whatsoever that teaches or suggests that inhibiting glucosylceramide synthase expression by an RNA antisense molecule against the glucosylceramide synthase mRNA has a therapeutic effect for treating epithelial tissue damage, let alone a preventative effect for preventing epithelial tissue damage from ever occurring in a person. That is, the instant specification fails to show the necessary nexus between reduced glucosylceramide synthase mRNA expression and the required

epithelial tissue damage treatment and prevention as claimed in the instant case. Applicant's support for the alleged "sufficient information" is entirely based on the hypothetical, unproven theory that one can block the function of CD1d by reducing glucosylceramide synthase mRNA. See applicant's statement on page 9 of the reply for example: "the specification clearly states that CD1d appears to negatively regulate cell apoptosis such that CD1d supports a continued existence of stressed cells". Most important, applicant's arguments taken as a whole suggest that promoting, not inhibiting, glucosylcermaide synthase is beneficial. See page 9 of the arguments, wherein applicant states that glucosylceramide synthase produces or synthesizes glucosylceramide, which is "capable of blocking the CD1d receptors" thus reducing inflammatory responses and thus blocking CD1d function that "supports a continued existence of stressed cells". Hence, applicant is supporting the idea that glucosylceramide production or biosynthesis is beneficial for reducing epithelial tissue damage, wherein glucosylceramide production/biosynthesis is mediated by glucosylceramide synthase, which therefore should be increased for more production of the beneficial glucosylceramide production, not reduced as claimed in the instant case. In addition to the applicant's argument for increasing glucosylceramide production on page 9, applicant also provides self-contradictory statements. Compare the statement "GlcCer induce cell proliferation and inhibit programmed cell death." to the statement "GlcCer is capable of promoting apoptosis". See last paragraph on page 9. Indeed, applicant explicitly states that "GlcCer is capable of promoting apoptosis, which is desirable in instances where cells have experienced damage but are capable of proliferating to potentially cause ageing and/or tumor development." Hence, applicant's arguments are not only based on conflicting statements but also suggest promoting glucosylceramide that is synthesized

by glucosylceramide synthase because the promoted production of glucosylceramide is desirable for treating epithelial tissue damage, which is the opposite concept of the theory underlying the claimed invention. It is questionable how applicant is able to make the conclusion stated on the following page, page 10, such that an antisense RNA that inhibits glucosylceramide synthase, which in turn reduces the production of glucosylceramide, wherein the reduced glucosylceramide is able to reduce damaged cell proliferation when applicant has explicitly stated that "GlcCer is capable of promoting apoptosis, which is desirable in instances where cells have experienced damage but are capable of proliferating to potentially cause ageing and/or tumor development." on the preceding page. Furthermore, applicant has not addressed how the claimed antisense RNA molecule is capable of "preventing" (stopping from occurrence, see the dictionary citation of record) epithelial tissue damage. In view of the foregoing, even if antisense-based therapeutics were assumed to be sufficiently developed at the time the invention was made, one of ordinary skill in the art would have not been able to treat, let alone prevent, the instantly claimed epithelial tissue damage that broadly embraces any kind of damage (e.g., burns, cuts, inflammation, scars, bruises, tumor formation) of any kind of epithelial tissue (e.g., kidney epithelial tissue, lung epithelial tissue) without undue experimentation. Hence, this rejection is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, 7am-3:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

/J. E. Angell/
Primary Examiner, Art Unit 1635